Vol. 44, Page 146 (1961), or the method described under ''Chick-Edema Factor—Bioassay Method (34)—Official Final Action'' in §§ 28.113–28.117, ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 12th Ed., 1975, pp. 509–511, which is incorporated by reference, shall be employed. (Copies of the methods are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspectionat the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*) The presence of chick-edema factor shall be determined by a comparison between the mean log of the pericardial fluid volumes of a test group and of a concurrent negative control group. The significance of the difference in pericardial fluid volumes between the test group and the negative control group is determined by calculating a ''*t*'' value according to the formula:

$$t = \frac{\bar{x}_t - \bar{x}_c}{\sqrt{\left(s_t^2/n_t\right) + \left(s_c^2/n_c\right)}}$$

where:

$\bar{x}_t$ and $\bar{x}_c$ are the means of the logs of the pericardial fluid volumes of the test and control groups, respectively;

n_t and n_c are the number of chicks in the respective groups;

s_t^2 and s_c^2 are the variances of the test and control groups, respectively.

The variances are calculated as follows:

$$s^2 = \frac{n(\sum x^2) - (\sum x)^2}{n(n-1)}$$

where:

Σx is the sum of the logs of the pericardial fluid volumes;

Σx^2 is the sum of the squares of the logs of the pericardial fluid volumes for either the test *t* or control *c* group data.

The test sample is judged to contain chick-edema factor if the calculated ''*t*'' exceeds +1.3 and the mean log of the pericardial fluid volume obtained from the negative control group multiplied by 100 is less than 1.1461.

(iii) ''Other factors toxic to chicks'' referred to in paragraph (b)(3) of this section shall be determined during the course of the bioassay test described in paragraph (b)(4)(ii) of this section, on the basis of chick deaths or other abnormalities not attributable to chick-edema factor or to the experimental conditions of the test.

(c) It is used or intended for use as a supplementary source of fat for animal feed.

(d) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label and labeling of the additive, and any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall bear:

(i) The name of the additive.

(ii) The designation ''feed grade'' in juxtaposition with the name and equally as prominent.

(2) The label or labeling of the additive and any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall bear adequate directions for use.

[41 FR 38652, Sept. 10, 1976, as amended at 47 FR 9397, Mar. 5, 1982; 54 FR 18281, Apr. 28, 1989; 70 FR 40880, July 15, 2005; 70 FR 67651, Nov. 8, 2005]

§ 573.660 Methyl glucoside-coconut oil ester.

Methyl glucoside-coconut oil ester may be safely used in accordance with the following conditions:

(a) The additive meets the specifications prescribed in § 172.816 of this chapter.

(b) It is used as a surfactant in molasses intended for use in animal feed at a level not to exceed 320 parts per million.

§ 573.680 Mineral oil.

Mineral oil may be safely used in animal feed, subject to the provisions of this section.

(a) Mineral oil, for the purpose of this section, is that complying with the definition and specifications contained in § 172.878 (a) and (b) or in § 178.3620(b)(1) (i) and (ii) of this chapter.

(b) It is used in animal feeds for the following purposes:

(1) To reduce dustiness of feeds or mineral supplements.

(2) To serve as a lubricant in the preparation of pellets, cubes, or blocks and to improve resistance to moisture of such pellets, cubes, or blocks.

(3) To prevent the segregation of trace minerals in mineralized salt.

(4) To serve as a diluent carrier in the manufacture of feed grade biuret in accordance with good manufacturing practice.

(5) For the removal of water from substances intended as ingredients of animal feed.

(c) The quantity of mineral oil used in animal feed shall not exceed 3.0 percent in mineral supplements, nor shall it exceed 0.06 percent of the total ration when present in feed or feed concentrates.

[41 FR 38652, Sept. 10, 1976, as amended at 47 FR 41106, Sept. 17, 1982]

§ 573.685 Natamycin.

The food additive natamycin (CAS No. 7681–93–8) may be safely used in broiler chicken feeds in accordance with the following specifications:

(a) The additive is a stereoisomer of 22-[(3-amino-3,6,dideoxy-β-D-mannopyranosyl)oxy]-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.1.$0^{5,\ 7}$] octacosa-8,14,16,18,20-pentaene-25-carboxylic acid with the empirical formula $C_{33}H_{47}NO_{13}$.

(b) The additive shall conform to U.S.P. specifications.

(c) The additive (as part of a premix composed of calcium carbonate, natamycin, and lactose) is used for retarding the growth of *Aspergillus parasiticus* in broiler chicken feeds for up to 14 days after the addition of natamycin.

(d) Each pound (454 grams (g)) of the premix shall contain 434 (g) of calcium carbonate, 10 g of natamycin activity, and 10 g of lactose. The premix shall be mixed into broiler chicken feed at the rate of 1 pound (0.454 kilograms (kg)) per ton (908 kg) of feed to provide natamycin at a level of 11 parts per million (ppm). The premix shall be thoroughly mixed into the dry components of the broiler chicken feed before adding the liquid components. Broiler feeds to which the natamycin premix is added shall be used within 4 weeks of addition of the premix.

(e) To assure the safe use of the additive, the label or labeling of the additive shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the following:

(1) The name and CAS number of the additive, and its purpose.

(2) A listing of ingredients consisting of calcium carbonate, the additive, and lactose and their proportions in the premix as prescribed under paragraph (d) of this section.

(3) Adequate directions for use to ensure a broiler chicken feed that is in compliance with the limitations prescribed in paragraph (d) of this section.

(4) An appropriate cautionary statement: ''Caution: Store in a tightly-closed, light-resistant container in a cool, dry place.''

(5) An expiration date of 1 year from the date of manufacture.

(6) A contact address and telephone number for reporting adverse reactions experienced by users, or to request a copy of the Material Safety Data Sheet for natamycin.

[69 FR 19321, Apr. 13, 2004]

§ 573.700 Sodium nitrite.

Sodium nitrite may be safely used in canned pet food containing meat and fish in accordance with the following prescribed conditions:

(a) It is used or intended for use alone as a preservative and color fixative in canned pet food containing fish, meat, and fish and meat byproducts so that the level of sodium nitrite does not exceed 20 parts per million.

(b) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label of the additive shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive in any mixture.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (a) of this section.